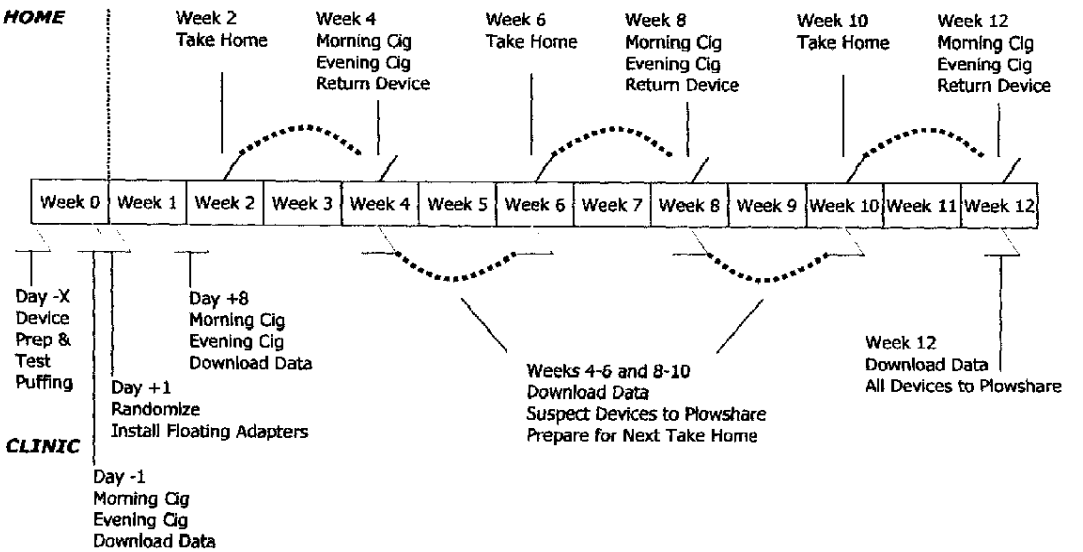
Protocol Overview



Procedures

Prep

- Connect device to host PC
    - If maintenance required, follow **Maintenance** procedure
- Synchronize date/time
- On Study Tab, set the Subject-ID to "PrepDevice" and Study Name to "TestCig"
- Disconnect device from host PC
- Install battery
- Perform smoking-machine test puffs, see **Puffing** procedure
- Remove battery
- Connect device to host PC
    - If maintenance required, follow **Maintenance** procedure
- Download and erase topography data
    - If data warnings reported, follow **Warning** procedure
- On Study Tab, Erase Study Info from device
- Disconnect device from host PC
- Follow **Dispense** procedure when ready for participant use

Source: https://www.industrydocuments.ucsf.edu/docs/rnpx0001

Dispense

- Connect device to host PC
- On the Study Tab, set the proper Subject-ID and Study Name on the device
- Disconnect device from host PC
- Label device with Subject-ID (use plastic or removable label)
- Include fresh battery with device for participant installation on device use
- Instruct participant in proper use of device

Download

- Confirm red LED is off (battery is still good)
    - Note locally and report to Plowshare by SN#/date
- Visually inspect for damage or excessive dirtiness
    - Note locally and report to Plowshare by SN#/date
- Remove battery
- Retain battery for subsequent use in next period
- Connect device to host PC
    - If maintenance required, follow **Maintenance** procedure
- Download topography data – do not erase
    - If data warnings reported, follow **Warning** procedure
- Disconnect device from host PC
- If Week 12/final visit, follow the **Return** procedure

Puffing (to be supplied by PMUSA)

Maintenance

- Apply red label to top of device, log SN#/date locally
- Download and erase topography data
    - If data warnings reported, apply yellow label to top of device
- On the Study Tab, leave the Subject-ID and set Special "TestCig" Study Name
- Disconnect device from host PC
- Install battery
- Perform smoking-machine test puffs, see **Puffing** procedure
- Remove battery
- Connect device to host PC
    - Ignore maintenance required message
- Download and erase topography data
    - Ignore data warning messages (if any)
- Disconnect device from host PC
- Return device to Plowshare
- Prepare a replacement device for use by subject, see **Prep** procedure

Source: https://www.industrydocuments.ucsf.edu/docs/rnpx0001

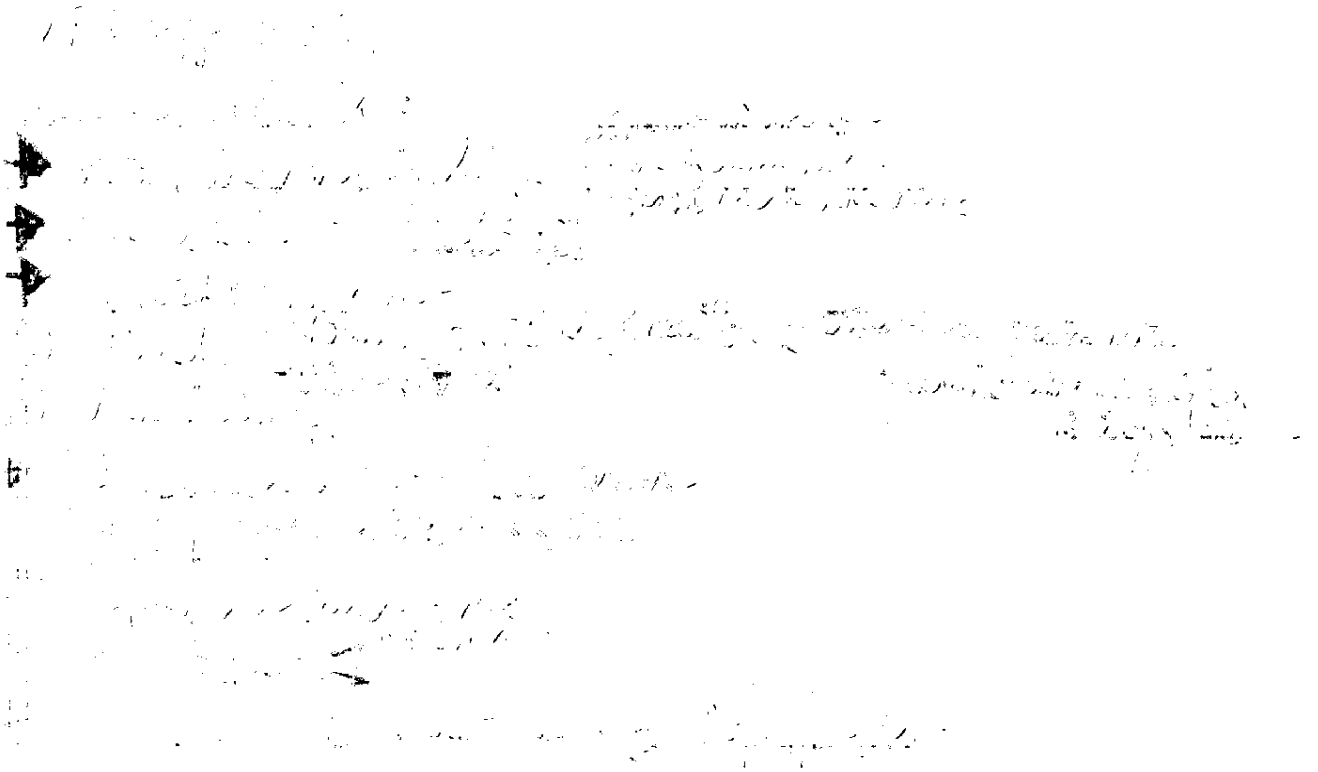
Warning

- Apply yellow label to top of device, log SN#/date locally
- Erase topography measures (if they've not yet been erased)
- On the Study Tab, leave the Subject-ID and set Special "TestCig" Study Name
- Disconnect device from host PC
- Install battery
- Perform smoking-machine test puffs, see **Puffing** procedure
- Remove battery
- Connect device to host PC
    - Ignore maintenance required message (if any)
- Download and erase topography data
    - Ignore data warning messages
- Disconnect device from host PC
- Return device to Plowshare
- Prepare a replacement device for use by subject, see **Prep** procedure

Return (for normal devices returned to Plowshare)

- After running the final **Download** procedure in Week 12, do following:
- Erase topography measures (if they've not yet been erased)
- On the Study Tab, leave the Subject-ID and set Special "TestCig" Study Name
- Disconnect device from host PC
- Install battery
- Perform smoking-machine test puffs, see **Puffing** procedure
- Remove battery
- Connect device to host PC
    - Ignore maintenance required message (if any)
- Download and erase topography data
    - Ignore data warning messages (if any)
- On the Study Tab, erase the Study Info from the device
- Disconnect device from host PC
- Return device to Plowshare

Source: https://www.industrydocuments.ucsf.edu/docs/rnpx0001



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